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September 28, 1999

Via Federal Express

Ms. Jennie Butler
Dockets Management Branch
Food and Drug Administration
Department of Health & Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99P-2554/CP

Dear Ms. Butler:

As you may know, on Monday this week, I filed a response to the complaint filed by Mr. Buttolph against my client, E. Excel International, Inc. Unfortunately, Dr. Jau-Fei Chen, the president of E. Excel, was out of the country and did not have a chance to review it prior to sending it to you. When she did review it, she found three errors which need correction. Those errors are described below. I have included with this letter new pages for the response letter which correct those errors. I am requesting that these pages be substituted into the prior letter to become the "official" version regarding this matter. To aid in this effort, I have included the pages which need to be substituted, and I also have included an entirely new letter (without exhibits) which could be substituted, whichever is easier for you.

The first error is found at page 4 of the letter in the first paragraph under the heading "General Background." In that paragraph, it is stated that Dr. Chen received her Ph.D. in Biochemistry. In fact, she received her doctorate in Microbiology.

The second error is found at page six in the numbered subparagraph 4. E. Excel wants it to be made clear that not only has it not authored, sold or endorsed the E. Excel Product Information booklet, but also that it has never distributed it as well.

The third error is found in the first paragraph under the heading of "Substantiation." Therein is a sentence which reads: "E. Excel does not publish or distribute the E. Excel Product Information booklet anymore." The use of the word

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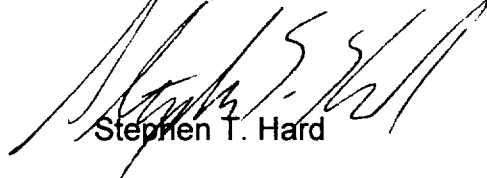
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"anymore" implies that at some time E. Excel did publish or distribute that booklet, which is not true. Accordingly, that sentence has been changed to omit the word "anymore."

Thank you for your assistance in allowing me to make these corrections to the record. Please call me if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen T. Hard", is written over the printed name.

Stephen T. Hard

cc: Dr. Jau Fei Chen

As can be seen, Mr. Buttolph has a clear propensity to misrepresent the facts. Thus, it is not surprising that he also misquotes and mischaracterizes E. Excel's philosophy and literature. Whether Mr. Buttolph's actions are intentional, reckless or grossly negligent or whether any of Mr. Buttolph's claims should be considered credible will be for the reader to determine after reviewing E. Excel's history and its specific responses to Mr. Buttolph's allegations.

GENERAL BACKGROUND

E. Excel was founded in 1987 and began doing business in 1989 selling nutritional supplements. Its founder is Jau-Fei Chen, Ph.D. Dr. Chen obtained her doctorate degree in Microbiology in 1988 from Brigham Young University, specializing in Immunology. See letters from Brigham Young University attached hereto as Exhibit 3. In other words, unlike several of her competitors, she has actually earned the title of "Doctor" through a rigorous course of academic study, rather than obtaining that title from mere self-designation or from honorary degrees.

Dr. Chen and E. Excel firmly believe, as does almost any reasonable person, that a person's health can be positively or negatively affected by the nourishment one provides to the body. Studies and the human experience reveal time after time that those who are not properly nourished often suffer from a wide variety of human ailments and certainly become more susceptible to infection and disease. Conversely, well-nourished individuals have stronger immune systems and are able to enjoy healthier lives and repel disease.

This is certainly not a unique concept. It is one shared by many others because it is inherently logical and reasonable. Indeed, the DHSEA itself notes these obvious facts:

Congress finds that--

.....
(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies

.....
(5) preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;
.....

the time that the new labelling laws became mandantory on March 23, 1999.² With respect to "Nutriall," since at least March 23, 1999, E. Excel attached stickers with the "Nutrition Facts" to its existing supply of boxes for Nutriall, and the new boxes have the Nutrition Facts imprinted on them. A copy of the sticker that has been attached to the Nutriall box is attached hereto as Exhibit 4.

2. Allegations that E. Excel makes improper medical claims.

Beginning at page four of his complaint, Mr. Buttolph attempts to construct a case that E. Excel is making unsubstantiated drug claims that the E. Excel products will cure diseases. He constructs his arguments on a foundation of sand. The bases for his arguments are:

1. A book authored by Jau-Fei Chen entitled Plant Foods & Immunology: A Scientific Approach. Mr. Buttolph ignores the fact that this book, which contains substantial scientific evidence of the link between nutrition and effects upon the immune system, makes no mention of E. Excel or any of its products. Such a publication was contemplated and addressed in Section 403B of the DHSEA (21 U.S.C. § 343-2) which clearly recognizes that books regarding herbs can be sold if they do not mention specific products.

2. An E. Excel publication entitled The Excellent Word. Mr. Buttolph attempts to paint a false and misleading picture by failing to quote extensive language in that publication which places the snippets cited by Mr. Buttolph into proper context.

3. Materials regarding E. Excel's long discontinued product "Phytocopia."

4. A document entitled E. Excel Product Information. Although Mr. Buttolph literally devotes pages of his complaint to quotations from this document, he fails to inform the reader that this document was not authored by E. Excel, not sold by E. Excel, not endorsed by E. Excel and not distributed by E. Excel.³

² As Mr. Buttolph knows (or should know) the nutrition statements currently required by the DHSEA were not required on dietary supplements until March 23, 1999. See Federal Register attached hereto as Exhibit 5.

³ Since receipt of Mr. Buttolph's complaint, E. Excel has been attempting to discover the sources of that document. It appears to originally have been created by an

4. Substantiation

In his final parting shot, Mr. Buttolph insinuates that somehow E. Excel acted improperly by not providing information to Ms. Mielziner of this agency. He states: "This is especially alarming since the chart [from the E. Excel Product Information booklet] referenced in the preceding section and many of the claims mentioned in this Citizen Petition were taken from promotional material delivered by E. Excel this past week to my organization." With all due respect, Mr. Buttolph is a liar. E. Excel does not publish or distribute the E. Excel Product Information booklet. Further, attached hereto as Exhibit 7 is a true and complete copy of the invoice/packing statement showing those materials provided to Mr. Buttolph when he ordered product from E. Excel on or about July 16, 1999. As can be seen, he ordered no brochures describing the products or promotional literature, only the food products themselves.⁵

Further, as discussed previously, E. Excel did provide its then-current video and marketing literature to Ms. Mielziner. It did not provide copies of brochures which it did not author or promote, and it did not provide copies of documents used in foreign countries.

⁵ Through its own investigation, E. Excel has learned that one of its independent distributors apparently supplied some of the unauthorized information to Mr. Buttolph. That distributor has advised E. Excel that she has not distributed the E. Excel Product Information booklet for a "very long time" and that she only sent it and some other information because Mr. Buttolph was so insistent on getting additional information about E. Excel. That distributor also has provided E. Excel a copy of the E. Excel Product Information booklet, representative pages of which are attached hereto as Exhibit 8. The bottom of those pages state: "The information contained within this material is included for reference and educational purposes only. It is not intended as a substitute for the advice of a qualified medical professional. E. Excel International does not endorse or advocate self-diagnosis or self-medication in any way. If you have a condition which requires medical diagnosis and treatment, it is important that you visit a licensed health professional. The opinions expressed by authors and contributing distributors do not necessarily reflect the opinions of E. Excel International", and "This data is for information only. It has been collected from various sources and is historical in nature. It is not intended to take the place of advice from a physician. This data is not produced by E. Excel International - nor is it distributed by them." (Emphasis added.)

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Recipient's
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Ms. Jennie Butler

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Dockets Management Branch
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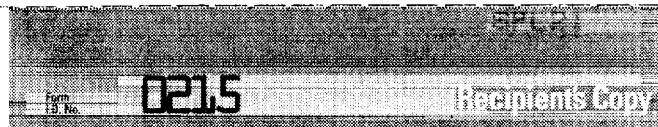
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